

NOV - 3 1999

K 991054

510(k) SUMMARY  
BRAVO MULTI-MODALITY SYSTEM

(a) INFORMATION REQUIRED FOR ALL SUMMARIES

- (1) Submitter's Name: Nicolet Biomedical Inc.  
Submitter's Address: 5225 Verona Road, Bldg. 2  
Madison, WI 53711 U.S.A.  
Submitter's Telephone Number: (608) 273-5000  
Contact Name: Douglas E. Pfrang  
Date summary was prepared: March 26, 1999
- (2) Trade or proprietary name: Bravo Multi-Modality System  
Common or usual name: Electroencephalograph (EEG)  
Evoked Potential (EP)  
Electromyograph (EMG)  
Transcranial Doppler (TCD)  
Classification name: Electroencephalograph (84GWQ)  
Evoked Potential Electrical Stimulator (84GWF)  
Evoked Potential Photic Stimulator (84GWE)  
Evoked Potential Auditory Stimulator (84GWI)  
Electromyograph (89GWP)  
Nonfetal Ultrasonic Monitor (90JAF)
- (3) Identification of the legally marketed devices to which equivalence is claimed.
1. Nicolet Spirit EMG/EP (FDA Log No. K905632)
  2. Nicolet Voyageur EEG (FDA Log No. K921927)
  3. Nicolet/EME Trans-Scan TCD (FDA Log No. K874685)

- (4) Description of the device, including an explanation of how the device functions, the scientific concepts, and the significant performance characteristics such as device design, material used, and physical properties.

The Bravo Multi-Modality System is a personal computer-based digital data recorder for continuously monitoring various types of neurological information, including:

(i) neuroelectric and neuromuscular data pertaining to the patient's central and peripheral nervous system and muscles, and (ii) neurovascular data pertaining to blood flow in the patient's brain and related blood vessels.

The intended use of this device is to record and display EEG, EMG, EP and TCD signals; and to import and display data from third-party monitoring devices, such as vital signs monitors. EEG signals are passively recorded using electrically-conductive electrodes that are placed in electrical contact with the patient's skin or nervous system. EMG and EP signals are recorded using electrically-conductive electrodes that are placed in electrical contact with the patient's skin, nervous system or muscles. EMG signals are passively recorded, while EP

signals are evoked using a light source, a sound source, or an electrical stimulator. TCD signals are actively recorded using a non-invasive ultrasound transducer that emits and records ultrasound energy. The ultrasound energy is applied externally to the skin, passes through the skin and body tissues, reflects off blood molecules moving in the blood stream, passes back through the body tissues and skin, and returns to the transducer. Movement of the blood molecules causes a frequency or “Doppler” shift in the returned ultrasound energy, which is detected and converted into a signal representing the velocity of the blood from which the ultrasound energy was reflected. Third-party monitoring devices, such as vital signs monitors, acquire and display a variety of physiological data from the patient. Importing and displaying such data is done by taking an output signal directly from such monitoring devices without any additional connections to the patient. Data obtained from the monitoring device is then displayed, analyzed or stored by the Bravo Multi-Modality System independently of how the third-party device handles the data.

- (5) Statement of the intended use, including a description of the patient populations, and diseases or conditions, that the device is intended to diagnose, treat, prevent, cure, or mitigate. If different from the predicate device, an explanation of why the differences are not critical to the intended use when the device is used as labeled.

The Bravo Multi-Modality System is intended to record and display EEG, EP, EMG and TCD data in the clinic and hospital (including the hospital room, operating room, emergency room, intensive care unit, neuro intensive care unit, critical care unit, etc.), and to import and display data from third-party monitoring devices. It is intended to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles. It differs from the predicate devices in that it contains multiple modalities in a single device, whereas each predicate device has a very limited number of modalities. Nevertheless, like the predicate devices, the Bravo Multi-Modality System is intended to involve competent human intervention before any impact on human health occurs (i.e., clinical judgment and experience must be used to check and interpret the system's output).

- (6) Comparison between the technological characteristics of the new and predicate devices, such as design, material, chemical composition, energy source, etc.

The technological characteristics of the new and predicate devices are substantially equivalent because the hardware and software in the Bravo Multi-Modality System is largely based on the predicate devices. The design, material, chemical composition, energy source, etc., are essentially unchanged. The main difference is that advances in computer technology (i.e., hardware and software) have enabled multiple software applications to run concurrently on a single computer platform, thereby making possible a single integrated system with multi-modality capabilities. Nevertheless, each modality, when compared to a predicate device of the same modality, has similar performance specifications, a similar set of user-adjustable parameters, and is designed to comply with substantially the same performance standards.

**(b) INFORMATION REQUIRED IF EQUIVALENCE IS BASED ON PERFORMANCE DATA**

**(1) Brief discussion of nonclinical tests.**

Nonclinical tests consist of various tests to verify program function, such as testing user inputs and recording various test signals. Tests are ongoing, but indicate that the device is performing as expected. Test results are summarized below in paragraph (b)(3).

**(2) Brief discussion of clinical tests including, if applicable, a description of the subjects, a discussion of safety or effectiveness data obtained, a discussion of any adverse effects or complications, and any other relevant information.**

Clinical tests will be used to validate the device's performance under simulated or actual use conditions. Because each of the individual modalities was derived from an existing product, historical data will be a primary validation tool. To provide the remaining validation, the device will be evaluated at different health care sites to solicit comments from actual users and to assess the performance of the device under actual use conditions.

**(3) Conclusions drawn from nonclinical and clinical tests that demonstrate the device is as safe and effective, and performs as well as or better than the legally marketed device(s) identified in (a)(3).**

Clinical and nonclinical results of testing the Bravo Multi-Modality System are showing that it performs substantially as expected; i.e., that it is substantially equivalent to the predicate devices in terms of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV - 3 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Douglas E. Pfrang  
Director, Regulatory and Legal Affairs  
Nicolet Biomedical, Inc.  
5225 Verona Road, Building 2  
Madison, Wisconsin 53711-4495

Re: K991054  
Trade Name: Bravo Multi-Modality System  
Regulatory Class: II  
Product Codes: GWQ, GWF, GWE, IKN, and JAF  
Dated: August 4, 1999  
Received: August 5, 1999

Dear Mr. Pfrang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

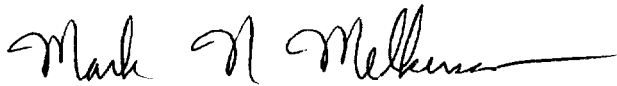
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Douglas E. Pfrang

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K 991054

Device Name: Bravo Multi-Modality System

Indications For Use:

The Bravo Multi-Modality System is intended to record and display EEG, EP, EMG and TCD data in the clinic and hospital (including the hospital room, operating room, emergency room, intensive care unit, neuro intensive care unit, critical care unit, etc.), and to import and display data from third-party monitoring devices such as vital signs monitors. It is intended to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for* Mark A. Melanson  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991054

Prescription Use X  
Per 21 CFR 801.109

OR

Over-The-Counter Use \_\_\_\_\_